Application No.: 09/937,313
Inventor: BERNDL et al.
Reply to Office Action of 02 March 2006
Docket No.: 49860

Amendments to the Claims:

1-9 (canceled).

10. (previously presented) A process for producing an excipient adapted for use in a solid pharmaceutical dosage form, wherein said excipient is in the form of a free-flowing powder and consists essentially of

a pharmaceutically acceptable polymer and

from 10 to 50% by weight, based on the total weight of said excipient, of a liquid or semisolid solubilizing surface-active substance, wherein

the polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone, which is a water-soluble polymer with Fikentscher K values of from 12 to 100; which comprises

either spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or

processing the polymer and the surface-active substance in an extruder to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder.

11. (previously presented) The process according to claim 10, wherein the excipient comprises a surface-active substance which has a drop point in the range from 20 to 40°C.

12. (previously presented) The process according to claim 10, wherein the excipient comprises a surface-active substance which has an HLB of from 10 to 15.

13. (canceled)

14. (previously presented) The process according to claim 10, wherein the excipient comprises from 15 to 40% by weight of the surface-active substance.

15. (previously presented) The process according to claim 10, wherein the excipient comprises ethoxylated sorbitan fatty acid esters as surface-active substances.

16. (previously presented) The process according to claim 10, wherein the excipient comprises the products of the reaction of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid as surface active substance.

17. (previously presented) The process according to claim 10, wherein the excipient comprises from 20 to 30% by weight of the surface-active substances.

18. (previously presented) The process according to claim 10, wherein the excipient is in the form of a free-flowing powder of particles having a particle size of from 10 to 1000 μ.

19. (previously presented) A solubilizer-containing powder comprising the excipient obtained by the process of claim 10 and optionally one or more ingredients selected from the group consisting of flow regulators, dyes, mold release agents, fats, waxes, disintegrants, bulking agents and other tableting excipients.

20. (previously presented) The process according to claim 10, wherein the surface-active substance of the excipient is a non-ionic compound.

21. (currently amended) The process of claim 10, wherein said excipient is ~~not a pigment~~ free of pigment.

22. (new) A process for producing a free-flowing powder excipient for use in a solid

pharmaceutical dosage form comprising:

a pharmaceutically acceptable polymer, and

from 10 to 50% by weight, based on the total weight of the excipient, of a liquid or semisolid solubilizing surface-active substance, wherein

the pharmaceutically acceptable polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone, and

is a water-soluble polymer with Fikentscher K values of from 12 to 100

the process comprising producing the free-flowing powder excipient by one of:

spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or

extruding the polymer and the surface-active substance to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder, wherein

the surface active substance is in a suitable concentration to keep the excipient free flowing.

23. (new) The process of claim 22, wherein the concentration of surface active substance is 15 to 40% by weight based on the weight of the excipient.

24. (new) The process of claim 22, wherein the concentration of surface active substance is 20 to 30% by weight based on the weight of the excipient.

25. (new) A process for producing a free-flowing powder excipient for use in a solid pharmaceutical dosage form comprising:

a pharmaceutically acceptable polymer,

a liquid, and

from 10 to 50% by weight, based on the total weight of the excipient, of a liquid or semisolid solubilizing surface-active substance, wherein

the pharmaceutically acceptable polymer in the excipient is a homo- or

copolymer of N-vinylpyrrolidone, and

is a water-soluble polymer with Fikentscher K values of from 12 to 100

the process comprising producing the free-flowing powder excipient by one of:

spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or

extruding the polymer and the surface-active substance to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder, wherein

the surface active substance is in a suitable concentration to keep the excipient free flowing, and wherein

the liquid is combined with the powdered excipient.

26. (new) The process of claim 25, wherein the concentration of surface active substance is 15 to 40% by weight based on the weight of the excipient.

27. (new) The process of claim 25, wherein the concentration of surface active substance is 20 to 30% by weight based on the weight of the excipient.

28. (new) The process of claim 25, wherein the liquid is an oil.